Using the PercuSurge GuardWire System

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Site Experience

St. Joseph's/Mercy Hospital Site #25

- 6 Roll-In/Learning Patients
- 34 GuardWire Patients (68 Total Randomized)
- 2 Emergency Use Cases

- 5 Animal Studies/Research

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47 Total GuardWire Experience

Using the GuardWire A New Technology

- Learning Curve
- Characterizing Device Malfunctions
  - Adverse Events
  - Risk/Benefit Analysis

Learning the Technology

Operator

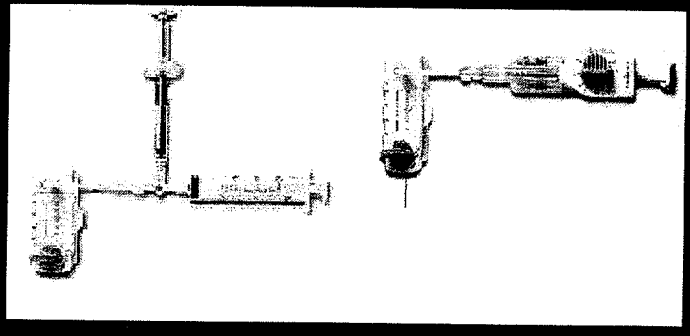
- First of a Kind Device
- New Treatment Category
- Average Roll-In per site of 4.5 patients
- Trial results support 5 learning cases/site

Device

- Balloon Occlusion
- Wire Performance
- Aspiration

Device

GuardWire 1 GuardWire Plus



Device Malfunction

Device malfunction was defined as the failure of a device to meet any of its performance specifications or otherwise perform as intended

Type of Malfunction

- Type I: Out of Body during Prep/Treatment
  - -contamination, MicroSeal kink, milky balloon, wrong size-type
- Type II: In Body without Sequelae
  - -non-occlude, could not cross, MicroSeal kink, MicroSeal leak, protocol unapproved devices (laser), non-protected balloon inflations
- Type III: In Body with Sequelae
  - -occlusion balloon dissection, break, non-occlude, rupture, could not cross

A Closer Look by Patient, Device Malfunction

	GuardWire (n=253)		GuardWire Plus (n=144)	
	n	% of 253	n	% of 144
Type I	23	9.1%	4	2.7%
Type II	27	10.6%	13	9.0%
Type III	36	14.2%	11	7.6%

Device Malfunctions

- Very Broad Definition
  - Contamination (dropped on floor)
  - Wrong size chosen for vessel
  - Use of other devices without protection
  - Milky Balloon
- Includes Malfunctions with No Potential to Affect Patient (i.e. during device prep)
- Intended to Learn as Much as Possible about the Device

Device Malfunction MACE by Patient